

REMARKS

The Office Action mailed November 9, 2009 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1-21 are currently pending. Claims 19 and 21 are amended herein, and new claim 22 is added, support for which can be found in the originally filed application at, for example, pp. 9-11, FIGS. 1-3. Claim 20 is canceled without prejudice herein. Applicants submit that no new matter is introduced.

Claim Rejections - 35 U.S.C. § 102

Claims 1-3, 5-8, 10-15, and 19-21 stand rejected under 35 U.S.C. 102(b) as being anticipated by USPN 5,534,007 to St. Germain et al. (hereinafter, "St. Germain"). Applicants respectfully traverse this rejection.

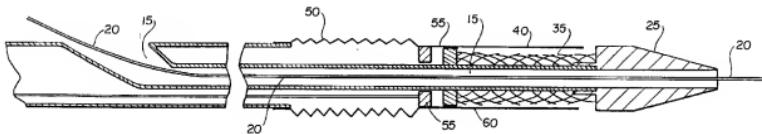
Independent claim 1 recites, *inter alia*, "the shaft defining a flushing lumen and a proximal guidewire exit port that is distal of the proximal end of the shaft for rapid exchange of the catheter with respect to the guidewire. . . and a second shaft element including a pusher tube to push the medical implant distally to prevent the medical implant from moving proximally with the sheath when the sheath is pulled proximally by the first shaft element."

The Office Action alleges that St. Germain teaches a proximal guidewire exit port and a second shaft element including a pusher tube. The Office Action references St. Germain FIG. 8 in support of the proximal guidewire exit port, and references numeral 155, shown and described as "catheter 155 comprised of a guide wire lumen 15 and a pull back lumen 150" (St. Germain, col. 6:8-9, FIGS. 6-7) in support of a second shaft element including a pusher tube. Applicants respectfully submit that St. Germain does not anticipate independent claim 1 at least because the St. Germain FIG. 8 embodiment does not include a pusher tube as claimed.

St. Germain shows and describes two types of stent deployment catheters, identified as "over-the-wire (OTW) catheters and rapid-exchange (RX) catheters" and states that the "key features of the longitudinally collapsible sheath" could be incorporated into both. (St. Germain, col.

6, l. 63 to col. 7, l. 10.) St. Germain FIG. 8, reproduced below, illustrates a rapid exchange embodiment of the invention, showing a guide wire lumen 15 that “is between approximately 5 cm to 35 cm from the distal tip 25 to a point where the guide wire lumen 15 and the guide wire 20 exit the catheter.” (St. Germain, col. 6:42-49.) The overall length of the catheter is said to be approximately 135 cm.

Fig. 8



St. Germain appears to show in FIG. 8 a “proximal guidewire exit port that is distal of the proximal end of the shaft for rapid exchange of the catheter with respect to the guidewire;” however, it is clear that FIG. 8 does not also illustrate “a second shaft element including a pusher tube,” as claimed. The Office references the catheter 155 of FIGS. 6-7 for this missing element. However, first, catheter 155 is not a pusher tube. Differently, catheter 155 has a stent receiving portion 30 around which a stent is concentrically arranged (St. Germain, col. 6:15-17), and includes a lengthwise guide wire lumen to provide an over-the-wire type configuration. Second, even assuming *arguendo* that catheter 155 *could* be considered a pusher tube, it clearly does not include a proximal guidewire exit port as claimed.

Applicants submit that while the collapsible sheath feature can be included in either the RX or OTW catheter configuration of St. Germain, the guidewire exit point is a defining feature that distinguishes the types of catheters. Whether the intention in the Office Action was to create a guidewire exit port in the FIG. 7 embodiment or substitute the catheter 155 for the catheter in the FIG. 8 embodiment, both modifications would require a substantial reconstruction and design of the St. Germain stent deployment catheter. Accordingly, St. Germain does not anticipate independent

claim 1 because neither of the RX or OTW embodiments show or describe each and every element of the claim.

With respect to independent claims 19 and 21, each is directed to a rapid exchange catheter including a shaft defining a proximal guidewire exit port and a pusher tube. Thus, each is patentable over St. Germain at least for the reasons set forth above.

In view of the above, Applicants respectfully submit that independent claims 1, 19, and 21, and claims 2-3, 5-8, and 10-15 depending from claim 1, are patentable over St. Germain, and therefore request favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 102.

Claim Rejections - 35 U.S.C. § 103

Claims 4, 9, and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain. Claims 17-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain in view of USPN 6,514,196 to Sullivan et al. Applicants traverse these rejections.

Regarding claim 4, the Office Action states that it would have been obvious to have an outer puller ring because “it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.” (Office Action, p. 4.) However, the outer pull ring of claim 4 is not a *duplication* of the inner pull ring, but rather works in conjunction to compress the sheath therebetween. In other words, the outer pull ring is a distinct feature from the inner pull ring, rather than merely a second inner pull ring as the Office Action appears to allege.

Regarding claim 9, the Office Action states that it would have been obvious to keep a pusher tube and pusher guide tube separate, and further that parts 140, 60, or 25 are capable of acting as an adaptor block. However, with reference to the discussion above in connection with independent claim 1, the RX embodiment of St. Germain FIG. 8 does not show a pusher tube. Moreover, contrary to the assertion in the Office Action, parts 140 (annular collar), 60 (stopper), and 25 (distal tip) are not capable of acting as the claimed adapter block at least because none have the requisite

structure, including “two lumens side-by-side, one for the pusher tube and the other for the pusher-guided tube.”

In any event, each of rejected claims 4, 9, and 16-18 depend from patentable independent claim 1, in view of the above, and are therefore patentable for at least this reason. Accordingly, without conceding the allegations in the Office Action or the propriety of the asserted combination of references, Applicants respectfully request favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicants of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Order No. 101671.0043P from which the undersigned is authorized to draw.

Dated: January 11, 2010

Respectfully submitted,

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